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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2006/022254	08.06.2006	08.06.2005

International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/00

Applicant
SHER, Philip Michael

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	see form PCT/ISA/210	Schwenke, Stephanie Telephone No. +31 70 340-4257

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	9-12, 21-24, 33-36
	No:	Claims	1-8, 13-20, 25-32
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	1-36
Industrial applicability (IA)	Yes:	Claims	1-36
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V.

1 Prior Art

Reference is made to the following document:

D1: US2005038332 SAIDARA, FRANK 17.02.2005

2 Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-8, 12-20, 24-32 and 36 is not new in the sense of Article 33(2) PCT.

2.1 to independent apparatus claim 1: The document D1 discloses (the references in parentheses applying to this document):

A continuos blood glucose monitoring system (see: at some frequent interval, the device measures the glucose level, par.[0090]), comprising:

- a system configured to continuously receive data from blood glucose monitoring sensors (see: glucose sensor, par.[0015]),
- the system being configured to convert sensor data into current blood glucose concentration values (implicit, see: devices which display data from measurements of a sensed physiological characteristic, e.g. blood glucose concentrations, par.[0015]),
- the system configured to support continuously fluctuating blood glucose notification threshold profiles (see: qualifying range; selected threshold rate, par.[0090]), the continuously fluctuating blood glucose concentration notification threshold profiles comprising: an upper blood glucose concentration threshold function (see: quality range can be a closed range, e.g. but not limited to, between 100 and 150mg/dL, par.[0091]), a lower blood glucose concentration threshold function (see: quality range can be a closed range, e.g. but not limited to, between 100 and 150mg/dL, par.[0091]), the threshold functions comprising specific values at specific times (see: threshold values and alarm can be set according to a schedule [...] particular alarms can be set to be active only during selected portions of the day, par.[0119])
- the system configured to compare a current blood glucose concentration value with a corresponding upper blood glucose concentration threshold value (see: if the most recent filtered value is in the qualifying range, par.[0090]),
- the system configured to compare a current blood glucose concentration value with a

corresponding lower blood glucose concentration threshold value (see: if the most recent filtered value is in the qualifying range, par.[0090]),
- the system configured to alert a user when a current blood glucose concentration value is greater than a corresponding upper blood glucose concentration threshold value (see: multiple qualifying ranges and threshold rates can be applied to evaluate the glucose dynamics and determine triggering a glucose crash warning, par.[0091]),
- the system configured to alert a user when a current blood glucose concentration value is less than a corresponding lower blood glucose concentration threshold value (see: multiple qualifying ranges and threshold rates can be applied to evaluate the glucose dynamics and determine triggering a glucose crash warning, par.[0091]).

The subject-matter of independent apparatus claim 1 is therefore not new in the sense of Article 33(2) PCT.

2.2 to independent method claim 13: the document D1 also includes:
A method of using a continuos blood glucose monitoring system (see: methods [...] convenient operation of monitoring physiological characteristics [...] glucose monitors, par.[0060]), comprising the steps of:
- defining a continuously fluctuating blood glucose notification threshold profile (see: qualifying range; selected threshold rate, par.[0090]) comprising: an upper blood glucose concentration threshold function (see: quality range can be a closed range, e.g. but not limited to, between 100 and 150mg/dL, par.[0091]), a lower blood glucose concentration threshold function (see: quality range can be a closed range, e.g. but not limited to, between 100 and 150mg/dL, par.[0091]), the upper and lower blood glucose concentration threshold functions forming the bounds of a expected blood glucose concentration range for the duration of the threshold profile (see: extrapolated curve is determined from a slop of a line fit, par.[0022]; a slope of a line fit [...] is calculated if the most recent of a series of physiological characteristic values exceeds a threshold value, par.[0023]), the threshold functions comprising specific values at specific times (see: threshold values and alarm can be set according to a schedule [...] particular alarms can be set to be active only during selected portions of the day, par.[0119]),
- activating the threshold profile (see: allow the user to customize the values, par.[0093])
- continuously receiving data from blood glucose monitoring sensors (implicit, see: devices which display data from measurements of a sensed physiological characteristic, e.g. blood

glucose concentrations, par.[0015]; see also: at some frequent interval, the device measures the glucose level, par.[0090])
- converting the sensor data to current blood glucose concentration values implicit, see: devices which display data from measurements of a sensed physiological characteristic, e.g. blood glucose concentrations, par.[0015])
- comparing a current blood glucose concentration value to a corresponding upper blood glucose concentration threshold value (see: if the most recent filtered value is in the qualifying range, par.[0090]),
- comparing a current blood glucose concentration value to a corresponding lower blood glucose concentration threshold value (see: if the most recent filtered value is in the qualifying range, par.[0090]),
- alerting the user if the current blood glucose concentration value is greater than the corresponding upper blood glucose concentration threshold value (see: multiple qualifying ranges and threshold rates can be applied to evaluate the glucose dynamics and determine triggering a glucose crash warning, par.[0091]),
- alerting the user if the current blood glucose concentration value is less than the corresponding lower blood glucose concentration threshold value (see: multiple qualifying ranges and threshold rates can be applied to evaluate the glucose dynamics and determine triggering a glucose crash warning, par.[0091]).

The subject-matter of independent method claim 13 is therefore not new in the sense of Article 33(2) PCT.

2.3 to independent device claim 25: the document D1 also includes:
A computer readable medium comprising executable processor code (implicit, see: data may be down loaded from the monitor, such as [...] programs, par.[0068]; programming routine performed by the processor of the monitor, par.[0094]) configured to support a continuos blood glucose monitoring system (e.g. see: REPEAT every minute [...] measure glucose [...] END REPEAT, par.[0094], Fig.1A) comprising:
- code for receiving data from continuos blood glucose monitoring sensors (implicit, see: Fig.1A; measure glucose level, par.[0094])
- code for converting blood glucose sensor data into current blood glucose concentration values (implicit, see: Fig.1A; measure glucose level, par.[0094])
- code supporting continuously fluctuating blood glucose notification threshold profiles

(see: range 100-150 mg/dL; -3% per minute, par.[0094]); the threshold profiles comprising: an upper blood glucose concentration threshold function (150 mg/dL, par.[0094]); a lower blood glucose concentration threshold function (100 mg/dL, par.[0094]); the threshold functions comprising specific values at specific times (see: threshold values and alarm can be set according to a schedule [...] particular alarms can be set to be active only during selected portions of the day, par.[0119]);

- code for comparing a current blood glucose concentration value with a corresponding upper blood glucose concentration threshold value (see: IF(g is in range 100-150mg/dL), par.[0094])
- code for comparing a current blood glucose concentration value with a corresponding lower blood glucose concentration threshold value (see: IF(g is in range 100-150mg/dL), par.[0094])
- code for alerting a user when a current blood glucose concentration is greater than a corresponding upper blood glucose concentration threshold value (see: THEN alert the patient, par.[0094])
- and code for alerting a user when a current blood glucose concentration is less than a corresponding lower blood glucose concentration threshold value (see: THEN alert the patient, par.[0094]).

The subject-matter of independent apparatus claim 25 is therefore not new in the sense of Article 33(2) PCT.

2.4 to dependent claims 2-8, 12, 14-20, 24, 26-32 and 36: the document D1 also discloses:

- claims 2, 3, , 14, 15, alerts: audible, tactile, vibratory, visual, par.[0117]
- claims 4-6, 16-18, 28-30, display: display data from measurements [...] line graph [...] bar graph [...] grid pattern, par.[0182]; graphical representation can comprise a color coded set, par.[0183], color coded set or indicators [...] can be indicated in red [...] yellow [...] orange [...] green
- claims 7, 8, , 19, 20, 31, 32, storage: memory for storing the physiological characteristic value data, par.[0030]
- claims 12, 24, 36, time: e.g but not limited to, 3 hours prior, par.[0100]

The subject-matter of dependent apparatus and method claims 2-8, 12, 14-20, 24, 26-32

and 36 is therefore not new in the sense of Article 33(2) PCT.

3 Inventive Step

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 9-11, 21-23 and 33-35 does not involve an inventive step in the sense of Article 33(3) PCT.

3.1 to dependent claims 9-11, 21-23 and 33-35: The document D1 is regarded as being the closest prior art to the subject-matter of these claims, and discloses the possibility for the user to define a threshold profile (see: allow the user to customize the values, par.[0093], allow the user to set the glucose threshold level and/or the threshold rate, par.[0105], multiple alarms can be independently set by the user, par.[0115]). The subject-matter of claims 9-11, 21-23 and 33-35 therefore differs in that it is explicitly stated based on which order of presentation of information (e.g. data or graphs) the user may select a threshold profile, whereas in the device, method and computer readable medium of D1 the order of presentation of information is different (see e.g.: user input can direct review of the alarm history, par.[0115], user scrolling through a list of snooze period increments, par.[0138]). The problem to be solved can therefore be seen as to provide a different presentation of information to the user who selects a threshold profile. The person skilled in the art would, without involving any inventive skill, combine the different forms of presentation of information present in D1 (e.g.: lists, par.[0138]; graphs, par.[0182]; real-time glucose display and history, par.[0174]) to find an alternative way of presenting the information to the user.

4 Final remarks

4.1 Should the applicant wish to request examination (Article 35 PCT) he should file with such a request an amended set of claims taking into account the points raised above and the requirements of Article 6 and 28(2) PCT. Claims should be drafted in accordance with Rule 6 PCT, in particular concerning the use of reference signs, the two part form and only one independent claim per category. Also with any such request for examination the description should be brought in accordance with the amended claims. A document representative of the closest prior art should be identified as such in the description and should be identified as the basis of the two part form of any independent apparatus claim, Rule 6.3(a)(i) PCT.